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**Attorneys for Plaintiffs**

EILEEN WARD,  
460 30<sup>th</sup> Street  
Manhattan Beach, California 90266

Plaintiff,

vs.

MEDICAL COMPONENTS, INC.,

1499 Delp Drive  
Harleysville, Pennsylvania 19438

Defendants,

COURT OF COMMON PLEAS  
PHILADELPHIA COUNTY

JULY TERM, 2024

NO:

JURY TRIAL DEMANDED

PETITION FOR DAMAGES

**NOTICE TO DEFEND**

**NOTICE:**

You have been sued in court. If you wish to defend against the claim set forth in the following pages, you must take action within twenty (20) days after this Complaint and Notice are served, by entering a written appearance personally or by attorney, and filing in writing with the Court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the Court without further notice for any money claimed in the Complaint or for any other claims or relief requested by the Plaintiff. You may lose money or property or other rights important to you.

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Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta ascantar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademias, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO IMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

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## **COMPLAINT – CIVIL ACTION**

Plaintiff EILEEN WARD (“Ms. Ward” or “Plaintiff”), for her Complaint against Defendant MEDICAL COMPONENTS, INC. (“MedComp” or “Defendant”), alleges as follows:

### **PRELIMINARY STATEMENT**

1. This is an action for damages arising out of MedComp’s failure to properly design, develop, test, assemble, manufacture, package, promote, market, distribute, supply, and/or sell the defective implantable vascular access device sold under the trade name Dignity Low Profile (the “Device”).

2. Plaintiff Eileen Ward seeks compensatory damages, punitive damages, disgorgement of profits, restitution, statutory damages, costs and expenses, reasonable attorneys’ fees, pre-judgment interest, post-judgment interest, and such other relief as the Court may deem just and proper.

### **PARTIES**

3. Eileen Ward is an adult resident of Manhattan Beach, California.

4. Defendant Medical Components, Inc. (“MedComp”) is a Pennsylvania corporation with its principal place of business in Harleysville, Pennsylvania. MedComp is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the Device.

### **JURISDICTION AND VENUE**

5. The Court has jurisdiction over this matter pursuant to 42 Pa. C.S.A. § 931(a).

6. Venue is proper in this Court pursuant to Pa. R. Civ. P. 2179(a)(2) because MedComp regularly conducts business in the County of Philadelphia.

7. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over MedComp because MedComp is present in the State of Pennsylvania and requiring an appearance does not offend traditional notices of fair and substantial justice.

### **PRODUCT BACKGROUND**

#### **The Device**

8. In or about 2011, MedComp received clearance via the 501(k) Premarket Notification Program from the Food and Drug Administration (FDA) to market and sell Device. The Devices were designed, patented, manufactured, labeled, marketed, sold, and distributed by MedComp at all relevant times herein.

9. The Device is a totally implantable vascular access device intended to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products. The Device is surgically placed under the skin and left implanted. It consists of two primary components: an injection port and a catheter.

10. The injection port has a raised center, or “septum,” into which a needle may be inserted for delivery of medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter, which is inserted into a blood vessel.

#### **Regulatory Background**

11. MedComp obtained “clearance” to market the Device under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

12. Section 510(k) permits the marketing of a medical device without formal review for safety or efficacy if the new device is substantially equivalent to other legally marketed predicate devices. The FDA explained the difference between the 510(k) process and the more

rigorous “premarket approval” (“PMA”) process in an amicus brief filed with the Third Circuit in

*Horn v. Thoratec Corp.*:

A manufacturer can obtain an FDA findings of ‘substantial equivalence’ by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found to be ‘substantially equivalent’ to a predicate device is said to be ‘cleared’ by the FDA (as opposed to “approved” by the agency under a PMA).<sup>1</sup>

13. A pre-market notification submitted under 510(k) is therefore entirely different from a PMA, which must include data sufficient to demonstrate that the product involved is safe and effective.

14. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared, “the manufacturer remains under an obligation to investigate and report any adverse associated with the drug...and must periodically submit any new information that may affect the FDA’s previous conclusions about the safety, effectiveness, or labeling ....” This obligation extends to post-market monitoring of adverse events and complaints.

#### **MedComp’s Marketing of the Device**

15. MedComp marketed the Device to the medical community and to patients as safer and more effective than competing vascular access devices.

16. MedComp marketed and sold the Device to the medical community at large and to patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing

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<sup>1</sup> *Horn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004) (quoting FDA amicus brief).

organizations, and also include the provision of valuable consideration and benefits to the aforementioned.

### **Design and Manufacturing Defects**

17. Upon information and belief, the Device's catheter is made from a polymeric mixture of silicone or polyurethane and barium sulfate, a radiopaque compound that is visible to certain radiographic imaging technologies.

18. Barium sulfate is known to reduce the mechanical integrity of catheters *in vivo*. Particles of barium sulfate dissociate from the surface of the catheter over time, causing microfractures and other alterations to the polymeric structure of the catheter material.<sup>2</sup>

19. Upon information and belief, MedComp designed and manufactured the Device with dangerously high concentrations of barium sulfate. The excess barium sulfate does not properly bond with the polymer matrix comprising the catheter material. Once a catheter made of this unstable material is implanted in the body, barium sulfate particles dissociate from the catheter, causing surface irregularities.

20. Cracks, fissures, divots, and pitting on the surface of a catheter allows the proteins in the bloodstream to collect on the surface.

21. A build-up of proteins on a catheter surface can cause a dangerous blood clot, also called a thrombosis. The build-up of proteins also creates a favorable environment for colonization by infectious bacteria and fungal cells.

22. Although the surface degradation can be reduced or avoided with design modifications, MedComp elected not to incorporate those design elements into the Device.

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<sup>2</sup> See Hecker JF, Scandrett LA. Roughness and thrombogenicity of the outer surfaces of intravascular catheters. *J Biomed Mater Res.* 1985;19(4):381-395. doi:10.1002/jbm.820190404

23. Although the build-up of proteins can be reduced or avoided with design modifications, MedComp elected not to incorporate those design elements into the Device.

24. At all relevant times, MedComp could have designed—but did not design—the catheter of the Device with radiopaque materials other than barium sulfate so it would not degrade and thereby create a favorable environment for thrombosis and infection.

25. At all relevant times, MedComp could have designed—but did not design—the catheter of the Device with radiopaque materials other than barium sulfate so it would not degrade and thereby create a favorable environment for thrombosis and infection.

26. At all relevant times, MedComp could have designed—but did not design—the catheter of the Device with a sheath, coating, or other surface-modifying additives to prevent the build-up of proteins that create a favorable environment for colonization by infectious bacteria and fungal cells.

27. MedComp also failed to design and establish a safe, effective procedure for removal of Device. In the event of a failure, injury, or complications it is difficult to safely remove Device.

#### **MedComp's Knowledge of the Device's Defects**

28. At all times relevant to this action, MedComp knew and had reason to know that the Device was not safe for the patients into whom they were implanted. Patients implanted with a Device port had an increased risk of suffering life-threatening injuries including, but not limited to, thrombosis, thromboembolic events, and infection. Many such patients need additional surgeries to remove the defective devices. Some patients have died.

29. Upon information and belief, soon after the Device was introduced to market, which was years before the Plaintiff was implanted with her device, MedComp began receiving adverse event reports (“AERs”) from health care providers regarding the Device. AERs were known to

MedComp and were reflected in publicly accessible databases.

30. Rather than alter the design of the Device to make it safer or adequately warn physicians of the dangers associated with the Device, MedComp continued to actively and aggressively market the Device as safe.

31. Multiple alternative designs for the Device have been feasible at all times relevant to this matter.

32. The conduct of MedComp, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff, and evidences malice, fraud, gross negligence, and oppressiveness. MedComp had actual knowledge of the dangers presented by the Device, yet consciously failed to act reasonably to adequately inform or warn the Plaintiff, her prescribing physicians, or the public at large of these dangers; establish and maintain an adequate quality and post-market surveillance system; or recall the Device from the market.

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**SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF**

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33. MedComp advertised, promoted, marketed, sold, and distributed the Device as a safe medical device when MedComp knew or should have known the Device was not safe for its intended purposes and that the product could cause serious medical problems.

34. MedComp had sole access to material facts concerning the defective nature of the Device product and its propensity to cause dangerous side effects.

35. Before Ms. Ward was implanted with a Device, she was not informed of, and had no knowledge of, the complaints, known complications, and risks associated with Device, including, but not limited to the Device's dangerous propensity to cause infection.

36. Before Ms. Ward was implanted with the Device, her physicians were not aware of

its defective and dangerous condition.

37. In reliance on MedComp's representations, Ms. Ward's doctors were induced to, and did, surgically implant a Device in Ms. Ward's chest.

38. This occurred on or about June 15, 2022. The Device implanted in Ms. Ward had the reference number MRFP80PLN.

39. The Device was implanted by Michael Del Rosario, MD for the purpose of delivering chemotherapy that was required to treat Ms. Ward's breast cancer.

40. Dr. Rosario correctly and properly installed the Device in accordance with the manufacturer's instructions.

41. The Device implanted in Ms. Ward was in the same or substantially similar condition as when it left MedComp's possession and in the condition directed by and expected by MedComp.

42. At no time did Ms. Ward's healthcare providers place, maintain, or use the Device incorrectly or use the Device for an unforeseeable purpose.

43. At all times relevant, the Device was used for its intended purpose of providing repeated access to the Plaintiff's vascular system.

44. On or about July 27, 2022, Ms. Ward presented to Torrance Memorial Medical Center complaining of fever and chills. Samples taken from both the Plaintiff's blood and from the Device tested positive for MSSA bacteremia infection.

45. On or about July 28, 2022, Donny N. Baek, MD surgically removed the Device from Ms. Ward.

46. As the result of having the Device implanted, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone corrective

surgeries, and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

**CAUSES OF ACTION**

**COUNT I: DESIGN DEFECT – STRICT LIABILITY**

47. Plaintiff restates the allegations above as if fully rewritten herein.

48. MedComp developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, sold, and otherwise placed the Device into the stream of commerce for use by consumers, such as Plaintiff, in the United States (including in the Commonwealth of Pennsylvania).

49. Plaintiff was a foreseeable user of the Device.

50. At all relevant times, including when the Device left MedComp's control, the Device was defective in design and dangerous for use by the public in general and by Plaintiff in particular.

51. The Device was expected to and did reach the Plaintiff without substantial change in the condition in which it was developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, and sold by MedComp.

52. These design defects include but are not limited to the use of barium sulfate in the catheter; the absence of sheathing or coating surrounding the catheter; the absence of a surface-modifying additive surrounding the catheter.

53. The Device, as developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, and sold by MedComp, is defective in design and formulation and unreasonably dangerous because the Device did not perform as safely as an ordinary customer would have expected it to perform when used in an intended way.

54. Additionally, A reasonable manufacturer in MedComp's position would have concluded that the possibility and seriousness of harm posed by the Device outweighed the burden or cost of changing its design to make is safer.

55. The debilitating infection Ms. Ward experienced would not have occurred if the Device had not been defectively designed. Because of this defective design, the Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.

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**COUNT II: DESIGN DEFECT – NEGLIGENCE**

56. Plaintiff restates the allegations above as if fully rewritten herein.

57. MedComp had a duty to exercise reasonable care, including in its design, testing, and formulation of the Device, to ensure that it did not create unreasonable risk of harm to patients.

58. At all relevant times, MedComp failed to exercise reasonable care. Among other things, MedComp used degradable barium sulfate in the formulation of the catheter's surface material; failed to protect the catheter surface with a sheathing or coating; made the catheter surface of a material that promotes protein build-up and infection; and failed to coat the catheter with, impregnate it with, or other treat it with antimicrobial agent to combat the risk of serious infection.

59. MedComp knew or should have known the Device's design defects carried an unreasonable risk of harming the patient when the Device was used in a reasonably foreseeable manner.

60. As designer, developer, manufacturer, inspector, advertiser, distributor, and supplier of the Device, MedComp's knowledge of the product was superior to that of the Plaintiff

and the Plaintiff's healthcare providers, who did not know about the Device's design defects.

61. MedComp knew or should have known that the users of the Device, including the Plaintiff and the Plaintiff's healthcare providers, would not realize or discover on their own the design defects and dangers presented by the Device.

62. At the time of the design, manufacture, advertising, marketing, distribution, and sale of the Device, MedComp also aware that the Device

- a. Would be used without inspection for defects;
- b. Had previously caused serious infections in users;
- c. Had no established efficacy; and
- d. Would be implanted in patients where the risks outweighed any benefit or utility of the Device.

63. MedComp's negligent design of the Device was a substantial factor in causing Plaintiff's Injuries and Damages.

64. Plaintiff's Injuries and Damages would not have happened or occurred had MedComp not been negligent in designing the Device.

65. As a direct and proximate result of MedComp's negligent design, Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.

**COUNT III: FAILURE TO WARN/INSTRUCT – STRICT LIABILITY**

66. Plaintiff restates the allegations above as if fully rewritten herein.

67. At all relevant times, including when the Device left MedComp's control, the

Device was dangerous for use by the public in general and by Plaintiff in particular and came with defective warnings and/or instructions for its use.

68. The Device was expected to and did reach the Plaintiff without substantial change in the condition in which it was developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, and sold by MedComp.

69. The Device's informational defects include, but are not limited to, failing to warn (or inadequately warning) about the risk of catheter infection and thrombosis, or about the limited life expectancy of the Device.

70. MedComp knew that the warnings and/or instructions defects made The Device unreasonably dangerous to Plaintiff.

71. Physicians implanted the Device as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by MedComp.

72. At the time MedComp placed its defective and unreasonably dangerous Device into the stream of commerce, alternative warnings and/or instructions were feasible commercially, technologically, and scientifically.

73. These alternative warnings and/or instructions would have prevented and/or mitigated the harm resulting in the Plaintiff's injuries and damages without substantially impairing the reasonably anticipated or intended function of the Device.

74. Had the Plaintiff received proper or adequate warnings and/or instructions as to the risks of the Device, she would have heeded the warnings and/or instructions.

75. Had the Plaintiff received proper or adequate warnings and/or instructions as to the risks of the Device, her healthcare providers would have heeded the warnings and/or instructions.

76. Had the Plaintiff's healthcare providers received proper or adequate warnings

and/or instructions as to the risks of the Device, they would not have prescribed the Device or implanted it in Plaintiff and/or chosen a different path of treatment.

77. The inadequate warnings and instructions for the Device were a substantial factor in causing Plaintiff's injuries.

78. The Plaintiff's injuries would not have occurred had the warnings and instructions for the Device been adequate.

**COUNT IV: FAILURE TO WARN/INSTRUCT – NEGLIGENCE**

79. Plaintiff restates the allegations above as if fully rewritten herein.

80. MedComp had a duty to exercise reasonable care, including in its warnings, instructions, and labeling of the Device to ensure that the devices did not create unreasonable risks of harm to others.

81. Medcomp's duty to warn existed before, during, and after the time of sale of the Device.

82. At all times relevant hereto, MedComp failed to exercise reasonable care by, among other things, failing to provide an adequate warning of the significant and dangerous risks of the Device; failing to provide adequate instructions to avoid the harms that could foreseeably occur from using the Device; otherwise failing to exercise reasonable and prudent care in the labeling of the Device; failing to exercise reasonable care when advertising and promoting the Device; and failing to perform reasonable pre- and post-market testing of the Device to determine whether the warnings and/or instructions were adequate for reasonably safe use.

83. MedComp knew or should have known of the Device's informational defects could cause harm when the Device was used in a reasonably foreseeable manner.

84. As designer, developer, manufacturer, inspector, advertiser, distributor, and

supplier of the Device, MedComp's knowledge of the Device was superior to that of the Plaintiff and the Plaintiff's healthcare providers.

85. At the time of the design, manufacture, advertising, marketing, distribution, and sale of the Device, MedComp knew or should have known the Device included inadequate warnings and/or instructions regarding the risk of infection and thrombosis.

86. These informational defects were not known or recognizable to the Plaintiff or her healthcare providers.

87. MedComp knew or should have known that the users of the Device, including the Plaintiff and the Plaintiff's healthcare providers, would not realize or discover on their own the informational defects and dangers presented by the Device.

88. Had the Plaintiff's healthcare providers received proper or adequate warnings and/or instructions as to the risks of the Device, they would not have prescribed the Device or implanted it in Plaintiff. They also may have chosen a different path of treatment.

89. MedComp's negligent warnings and/or instructions regarding the Device were a substantial factor in causing Plaintiff's injuries.

90. The Plaintiff's injuries would not have occurred had MedComp not been negligent in warning and/or instructing regarding the Device.

91. As a direct and proximate result of MedComp's negligent warnings and/or instructions regarding the Device, the Plaintiff suffered injuries.

**COUNT V: MANUFACTURING DEFECT – STRICT LIABILITY**

92. Plaintiff restates the allegations above as if fully rewritten herein.

93. At all relevant times, MedComp manufactured, distributed, sold, and otherwise placed The Device (including the Device surgically implanted in Plaintiff) into the stream of

commerce for use by consumers, such as Plaintiff, in the United States (including in the Commonwealth of Pennsylvania).

94. Plaintiff was a foreseeable user of the Device.

95. When the Device left MedComp's control, the Device contained a manufacturing defect and was dangerous for use by the public in general and by Plaintiff in particular.

96. The Device was expected to and did reach the Plaintiff without substantial change in the condition in which it was manufactured, distributed, and sold by MedComp.

97. The Device's manufacturing defects include but are not limited to deviation from MedComp's specifications for the concentration of barium sulfate in the catheter and for the homogeneity of the barium sulfate distribution throughout the catheter.

98. These manufacturing defects existed even if MedComp exercised reasonable care.

99. The Device was defective in manufacturing and unreasonably dangerous because the Device contained a condition that MedComp did not intend.

100. The Device was defective in manufacturing and unreasonably dangerous because the Device was more dangerous than the ordinary customer would expect.

101. MedComp knew that the manufacturing defects made the Device unreasonably dangerous to Plaintiff.

102. Physicians implanted the Device as instructed according to the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by MedComp.

103. The defective and unreasonably dangerous condition of the Device was a substantial factor in causing the Plaintiff's injuries.

104. The Plaintiff's injuries would not have occurred had the Device not been defective

and unreasonably dangerous.

105. As a direct and proximate result of the defective and unreasonably dangerous condition of the Device, the Plaintiff suffered injuries.

**COUNT VI: MANUFACTURING DEFECT – NEGLIGENCE**

106. Plaintiff restates the allegations above as if fully rewritten herein.

107. MedComp had a duty to exercise reasonable care in their manufacture of the Device to ensure that it did not create unreasonable risks of harm to patients. That duty extended to the manufacture of the Device that was surgically implanted in the Ms. Ward.

108. At all times relevant hereto, MedComp failed to exercise reasonable care by, among other things:

- a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of product failure;
- b. Failing to implement adequate procedural safeguards to ensure that the Device did not differ from MedComp's design or specifications or from other typical units from the same production line;
- c. Failing to establish an adequate quality-assurance program used in the manufacturing of the Device;
- d. Failing to implement adequate procedural safeguards, including but not limited to quality-control testing, to ensure that the Device met MedComp's specifications for barium-sulfate concentration; and
- e. Failing to implement adequate procedural safeguards, including but not limited to quality-control testing, to ensure that the Device met MedComp's specifications for the homogeneity of barium sulfate throughout the surface of the catheter.

109. MedComp knew or should have known the Device was manufactured in a manner that created an unreasonable risk of infection, thrombosis and death.

110. These manufacturing defects were not known or recognizable to the Plaintiff or her healthcare providers.

111. MedComp knew or should have known that the users of the Device, including the Plaintiff and her healthcare providers, would not realize or discover on their own the manufacturing defects and dangers presented by the Device.

112. At the time of the design, manufacture, advertising, marketing, distribution, and sale of the Device, MedComp was also aware that the Device would be used without inspection for these defects.

113. MedComp's negligent manufacturing of the Device was a substantial factor in causing the Plaintiff's injuries.

114. The Plaintiff's Injuries and Damages would not have occurred had MedComp not been negligent in manufacturing The Device.

115. As a direct and proximate result of MedComp's negligent manufacturing of The Device, the Plaintiff suffered injuries.

**COUNT VII: BREACH OF EXPRESS WARRANTY**

116. The Plaintiff restates the allegations above as if fully rewritten herein.

117. The Plaintiff, through their medical providers, purchased the Device from MedComp.

118. At all relevant times, MedComp was a merchant of goods of a kind that includes medical devices and implanted port catheters (e.g., the Device).

119. At the time and place that it sold, distributed and supplied the Device to the Plaintiff and to other consumers and the medical community, MedComp expressly represented and warranted that the Device, among other things

- a. Was safe and effective for its intended use;
- b. Was well-tolerated, efficacious, and fit for its intended purpose;
- c. Was of merchantable quality;
- d. Did not produce any unwarned-of dangerous side effects; and
- e. Was adequately tested.

120. MedComp expressly represented and warranted that, among other things

- a. The Device was less likely to become infected than external catheters;
- b. The risk of IPC infection was limited to physician or patient error;
- c. The Device was biocompatible;
- d. The Device was durable;
- e. The Device was safe and effective for long-term use; and
- f. MedComp conducted adequate post-market surveillance to ensure patient safety.

121. These warranties came in one or more of the following forms:

- a. Publicly-made written and verbal assurances of safety;
- b. press releases, statements in the media, and promotional information intended to create demand for the Device, which contained misrepresentations and failed to warn of the risks of using the Device;
- c. verbal assurances about the safety of the Device that also downplayed the risks associated with the product; and
- d. false, misleading, and inadequate written information and packaging supplied by MedComp.

122. When MedComp made these express warranties, it knew the intended purposes of the Device and warranted the Device to be in all respects safe and proper for such purposes.

123. MedComp drafted the documents and/or made statements upon which these warranty claims were based and, in doing so, defined the terms of those warranties.

124. At the time of Plaintiff's purchase from MedComp, the Device did not possess the characteristics or capabilities MedComp represented it to possess.

125. MedComp breached their expressed warranties insofar as the Device, among other things:

- a. Did not conform to MedComp's promises, descriptions, or affirmations;
- b. Was not adequately packaged, labeled, promoted, and/or fit for the ordinary purpose for which it was intended;
- c. Was designed in such a manner so as to be prone to an unreasonably high incidence of infection and thrombosis;
- d. Was manufactured in such a manner that the catheter was inadequately, improperly, and inappropriately constituted, causing it to degrade; and
- e. Carried a risk of use that outweighed any benefit.

126. MedComp's breach of express warranty was a substantial factor in causing the Plaintiff's injuries.

127. The Plaintiff's injuries would not have occurred had MedComp not breached its express warranties.

128. As a direct and proximate result of MedComp's breach of express warranty, the Plaintiff suffered injuries.

#### **COUNT VIII: BREACH OF IMPLIED WARRANTY**

129. The Plaintiff restates the allegations above as if fully rewritten herein.

130. The Plaintiff, through her medical providers, purchased the Device from MedComp.

131. At all relevant times, MedComp was a merchant of goods of a kind that includes medical devices and implanted port catheters (e.g., the Device).

132. At the time and place MedComp sold, distributed and supplied the Device to the

Plaintiff (and to other consumers and the medical community), MedComp impliedly warranted that the Device was, among other things:

- a. Fit for its ordinary and general purpose of providing repeated venous access;
- b. Safe and effective for its intended use; and
- c. Of merchantable quality.

133. MedComp knew or had reason to know that the Plaintiff would rely upon its judgment and skill in providing the Device for the intended use.

134. The Plaintiff reasonably relied upon the skill and judgment of MedComp as to whether the Device was fit for its ordinary and general purpose, safe and effective for their intended use, and of merchantable quality.

135. At the time the Plaintiff purchased the Device, it was neither of merchantable quality, nor safe and effective for their intended use, nor fit for a particular purpose.

136. MedComp breached its implied warranties by, among other things:

- a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that the Device would cause harm;
- b. Manufacturing and/or selling a Device that did not conform to representations made by MedComp when it left the Defendant's control;
- c. Manufacturing and/or selling a Device that was more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;
- d. Manufacturing and/or selling a Device that carried foreseeable risks associated with its design or formulation that exceeded the benefits associated with its design and formulation; and
- e. Manufacturing and/or selling a Device that deviated in a material way from the design specifications, formulas, or performance standards, or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards.

137. Neither the Plaintiff nor her health care providers could have discovered that MedComp breached its implied warranties.

138. MedComp's breach of its implied warranties was a substantial factor in causing Plaintiff's injuries.

139. Plaintiff's injuries would not have occurred had MedComp not breached its implied warranties.

140. As a direct and proximate result of MedComp's breach of implied warranties, Plaintiff suffered Injuries and Damages.

**COUNT IX: NEGLIGENT MISREPRESENTATION**

141. The Plaintiff restates the allegations above as if fully rewritten herein.

142. MedComp had a duty to exercise reasonable care to ensure that the Devices it manufactured did not create unreasonable risks of harm to patients. That duty of care required that it accurately inform the Plaintiff, her healthcare providers, and the public about the efficacy, risks, and harms associated with the Device.

143. At all times relevant hereto, MedComp breached its duty by negligently representing that, among other things,

- a. The Device was less likely to become infected than external catheters;
- b. The risk of IPC infection is limited to physician or patient error;
- c. The Device was biocompatible;
- d. The Device was durable;
- e. The Device was safe and effective for long-term use; and
- f. MedComp conducted adequate post-market surveillance to ensure patient safety.

144. These representations were untrue, as detailed further above.

145. MedComp knew or should have known that these representations were false and/or provided Plaintiff with incorrect information.

146. MedComp knew or should have known that these representations were false and/or provided Plaintiff's healthcare providers with incorrect information.

147. MedComp disseminated information concerning the Device to healthcare professionals and consumers, including to the Plaintiffs and her healthcare providers, directly and indirectly, orally and in writing, including but not limited to through sales representatives, reports, press releases, advertising campaigns, print advertisements, commercial media, marketing materials, labeling materials, instructions for use, and otherwise.

148. MedComp, as a medical device designer, manufacturer, seller, promoter and/or distributor, knew or should reasonably have known that the Plaintiff and her healthcare providers, in weighing the potential benefits and potential risks of prescribing or using the Device, would rely upon information disseminated and marketed by MedComp regarding the Device.

149. The Plaintiff and her healthcare providers reasonably and justifiably rely upon MedComp's negligent misrepresentations as to the Device.

150. MedComp's misrepresentations about the Device were material to the Plaintiff and her healthcare providers in that those representations influenced the Plaintiff and her healthcare providers' decisions to purchase and use the Device.

151. MedComp failed to exercise reasonable care to ensure that the information it disseminated to the Plaintiff and her healthcare providers concerning the properties and effects of the Device was accurate, complete, and not misleading. As a result, MedComp disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as the Plaintiff.

152. MedComp, as a medical device designer, manufacturer, seller, promoter, and/or distributor, also knew or reasonably should have known that patients receiving the Device would be placed in peril of developing serious, life-threatening, and life-long injuries, including, but not limited to infection and thrombosis, if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

153. MedComp had a duty to promptly correct material misrepresentations and/or incorrect information that they knew the Plaintiff, her healthcare providers, and others were relying upon in making healthcare decisions.

154. MedComp breached its duty by misrepresenting to the Plaintiff and the medical community the safety and efficacy of the Device and by failing to correct known misrepresentations and/or incorrect information.

155. At all times relevant hereto, the Plaintiff and her healthcare providers were unaware that MedComp's representations were false and were unaware of MedComp's omissions.

156. MedComp's negligent misrepresentations were a substantial factor in causing Plaintiff's injuries.

157. Plaintiff's injuries would not have occurred had MedComp not made negligent misrepresentations.

158. As a direct and proximate result of MedComp's negligent misrepresentations, the Plaintiff suffered injuries.

**COUNT X: FRAUDULENT MISREPRESENTATION**

159. Plaintiff restates the allegations above as if fully rewritten herein.

160. At all times relevant hereto, MedComp intentionally and/or with a reckless disregard for the truth misrepresented the Device to the Plaintiff, her healthcare providers, and the public, as detailed further above.

161. These representations were untrue, as detailed further above.

162. MedComp knew these representations were false and it willfully, wantonly, and recklessly disregarded the truth.

163. MedComp disseminated information concerning the Device to healthcare professionals and consumers, including to the Plaintiff her healthcare providers, directly and indirectly, orally and in writing, including but not limited to through sales representatives, reports, press releases, advertising campaigns, print advertisements, commercial media, marketing materials, labeling materials, instructions for use, and otherwise.

164. MedComp intended that the Plaintiff and her healthcare providers would rely upon its misrepresentations in their decisions concerning whether to prescribe and use the Device.

165. MedComp, as a medical device designer, manufacturer, seller, promoter and/or distributor, knew or should reasonably have known that the Plaintiff and her healthcare providers, in weighing the potential benefits and potential risks of prescribing or using the Device, would rely upon information disseminated and marketed by MedComp to them regarding The Device.

166. MedComp's intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including the Plaintiff and her healthcare providers; to gain the confidence of the public and the medical community; to falsely assure the public and the medical community of the quality of the Device and its fitness for use; and to induce the public and the medical community, including the Plaintiff and her healthcare providers, to

request, recommend, prescribe, implant, purchase, and continue to use the Device, all in reliance on MedComp's misrepresentations.

167. The Plaintiff and her healthcare providers reasonably and justifiably relied upon MedComp's fraudulent misrepresentations in using the Device.

168. MedComp's misrepresentations about the Device were material to the Plaintiff and her healthcare providers in that those representations influenced the Plaintiff's and her healthcare providers to purchase and use the Device.

169. At all times relevant hereto, the Plaintiff and her healthcare providers were unaware of the falsity of MedComp's representations and reasonably believed them to be true.

170. MedComp's fraudulent misrepresentations were a substantial factor in causing Plaintiff's injuries.

171. The Plaintiff's injuries would not have occurred had MedComp not made fraudulent misrepresentations.

172. As a direct and proximate result of MedComp's fraudulent misrepresentations, Plaintiff suffered injuries.

#### **COUNT XI: FRAUDULENT CONCEALMENT**

173. The Plaintiff restates the allegations above as if fully rewritten herein.

174. At all times relevant hereto, MedComp intentionally and fraudulently concealed material facts about the Device from the Plaintiff, her healthcare providers, and the public, including but not limited to the facts that

- a. The Device was unsafe and unfit for their intended purpose when used in a reasonably foreseeable manner;
- b. The Device posed dangerous health risks in excess of those associated with the use of other similar IPCs;

- c. Additional side effects related to implantation and use of the Device were not accurately and completely reflected in the warnings for the Device; and
- d. The Device was not adequately tested to withstand normal placement within the human body.

175. MedComp had a duty to disclose to the Plaintiff, her healthcare providers, and the public the truth about the Device. This duty arises out of, *inter alia*,

- a. MedComp's superior knowledge of and/or sole access to superior information regarding intrinsic qualities of the Device that are not readily ascertainable by customers, such as the Plaintiff;
- b. MedComp's partial disclosures;
- c. The nature of the facts themselves;
- d. MedComp's special relationship with the Plaintiff;
- e. The course of the parties' dealings; and
- f. The particular circumstances of the case.

176. MedComp's concealment of information regarding the Device was willful, wanton, and/or reckless.

177. MedComp intended that Plaintiff and her healthcare providers would rely upon its misrepresentations and omissions in their decisions to prescribe and use the Device.

178. The Plaintiff and her healthcare providers reasonably and justifiably relied upon MedComp's omissions in using the Device.

179. MedComp's omissions about the Device were material to the Plaintiff and her healthcare providers in that those representations influenced the Plaintiff and her healthcare providers decisions to purchase and use the Device.

180. At all times relevant hereto, the Plaintiff and her healthcare providers were unaware of the facts omitted and concealed by MedComp.

181. MedComp knew that the Plaintiff could not determine the truth of the foregoing information.

182. MedComp's fraudulent omissions were a substantial factors in causing the Plaintiff's injuries.

183. The Plaintiff's injuries would not have occurred had MedComp not made fraudulent omissions.

184. As a direct and proximate result of MedComp's fraudulent omissions, the Plaintiff suffered injuries.

**COUNT XII: CONSUMER PROTECTION STATUTES**

**Cal. Civ. Code § 1750 et seq.**

**Cal. Bus. & Prof. Code §§ 17200 et seq.; id. §§ 17500 et seq.**

**Pa. Stat. §§ 201-1 et seq.**

185. The Plaintiff restates the allegations above as if fully rewritten herein.

186. MedComp committed unfair and deceptive acts in violation of applicable consumer protection statutes, by, *inter alia*,

- a. Representing the Device has characteristics, uses, benefits and qualities it does not have;
- b. Representing the Device is of a particular standard, quality or grade when it is of another standard, quality or grade;
- c. Advertising goods with the intent to not serve them as advertised; and
- d. Causing likelihood of confusion or misunderstanding as to the approval or certification of the Device.

187. The Plaintiffs' purchase of the Device constitutes a sale within the meaning of all applicable law.

188. The Plaintiff is a consumer within the meaning of all applicable law.

189. MedComp's actions in violations of law were a substantial factor in causing the Plaintiffs' injuries.

190. Had MedComp not engaged in the fraudulent, unfair, and/or deceptive conduct described herein, neither the Plaintiff nor her healthcare providers would have purchased and/or paid for the Device.

191. The Plaintiffs' injuries would not have occurred had MedComp not violated the law.

192. As a direct and proximate result of MedComp's violation of the law, the Plaintiff suffered injuries.

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**COUNT XIII: UNJUST ENRICHMENT**

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193. The Plaintiff restate the allegations above as if fully rewritten herein.

194. The Plaintiff alleges this claim for unjust enrichment in the alternative.

195. Through its false and misleading statements, MedComp induced the Plaintiff and her healthcare providers to purchase the Device.

196. The sale of the Device by MedComp to the Plaintiff, through the intermediary healthcare providers, conferred a benefit on MedComp, including but not limited to profits from the sale.

197. MedComp knowingly received, accepted, and retained a benefit to which it was not entitled when it sold the Device to the Plaintiff.

198. It would be inequitable, unconscionable, and unjust for MedComp to retain the benefit of the sale of the Device to the Plaintiffs while the Plaintiffs suffered injuries from the device.

199. Plaintiff is entitled to restitution of the benefits MedComp unjustly retained, and/or any amounts necessary to return her to the position she was in prior to dealing with MedComp, and/or disgorgement of MedComp's profits from the Device.

#### **COUNT XIV: PUNITIVE DAMAGES**

200. Plaintiff restates the allegations above as if fully rewritten herein.

201. MedComp has acted maliciously, wantonly, willfully, oppressively, and with a reckless indifference to the interests of others, by, *inter alia*,

- a. failing to disclose material facts regarding the dangers and serious safety concerns of the Device;
- b. concealing and suppressing material facts regarding the dangers and serious health and/or safety concerns of the Device;
- c. making false representations with the purpose of deceiving Plaintiff into using the Device; and
- d. falsely representing the qualities and characteristics of the Device to the public and to the Plaintiff.

202. Such conduct justifies an award of punitive damages in an amount sufficient to punish MedComp's conduct and deter like conduct by MedComp and other similarly situated persons and entities in the future.

#### **DEMAND FOR JURY TRIAL**

The Plaintiff hereby demands trial by jury as to all counts of her Complaint.

#### **PRAYER**

**WHEREFORE**, The Plaintiff prays for judgment against MedComp on all causes of action of this Complaint and requests:

- a. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;
- b. Compensatory damages to Plaintiff for past, present, and future damages, including,

but not limited to, pain and suffering, mental anguish, disfigurement, impairment, medical expenses, lost wages, lost earning capacity, and loss of household services together with interest and costs as provided by law;

- c. Punitive damages;
- d. Disgorgement of profits;
- e. Restitution;
- f. Statutory damages, where authorized;
- g. Any and all applicable statutory and civil penalties, as allowed by law;
- h. Costs and expenses of suit;
- i. Reasonable attorneys' fees, where authorized;
- j. Pre-judgment interest as allowed by law;
- k. Post-judgment interest at the highest applicable statutory or common-law rate from the date of judgment until satisfaction of judgment; and
- l. Such other and further relief as the court may deem just and proper.

Dated: July 19, 2024

Respectfully submitted,

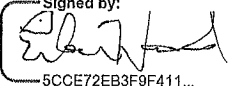
**LECKMAN LAW, LLC**

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**VERIFICATION**

I, Eileen Ward, hereby verify that I am the plaintiff in the foregoing action; that the attached Complaint is based upon information which I have furnished to my counsel and information which has been gathered by my counsel in the preparation of the lawsuit. The language of the Complaint is that of counsel and not of affiant. I have read the Complaint and to the extent that the allegations therein are based upon information I have given counsel, they are true and correct to the best of my knowledge, information, and belief. To the extent that the contents of the Complaint are that of counsel, I have relied upon counsel in making this Verification. I understand that false statements made herein are made subject to the penalties of 18 Pa. C.S.A. § 4904 relating to unsworn falsifications to authorities.

DATED: July 18, 2024

Signed by:  
  
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Eileen Ward